UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

2 Nov 2010

MEMORANDUM

SUBJECT: Correction to Parameters "Task Duration" and "Surface Area", and Verification of "AaiH" for EPA's 4 October 2010 Science Review of the AEATF II Mop Human Exposure Monitoring Study. MRIDs 48210201, 48231201, and 48231901

FROM: Tim Leighton, Environmental Scientist
Antimicrobials Division

TO: Nader Elkassabany, PhD, Chief
Risk Assessment and Science Support Branch
Antimicrobials Division

REF: Selim, S., and Taylor, M. (2010) A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Liquid Antimicrobial Pesticide Product Using Bucket and Mop Equipment for Cleaning Indoor Surfaces. Unpublished study prepared by Golden Pacific Laboratories, LLC, under Project No. AEA03, Report No. 070265. 2116 p. (MRIDs 48210201, 48231201, and 48231901)

Leighton, T. (2010) Science Review of the AEATF II Mop Human Exposure Monitoring Study. MRIDs 48210201, 48231201, and 48231901. Memorandum dated 4 October 2010 to Nader Elkassabany. 25 p.

This memorandum corrects and verifies three study parameters reported in the cited EPA Science Review of the human exposure mop study submitted by the Antimicrobial Exposure Assessment Task Force II (AEATF II). The attached tables report the corrected values for the task duration and surface area. My science review of 4 October 2010 used the correct AaiH; no changes have been made in the AaiH. Therefore, the dermal and inhalation exposure data as presented in the original EPA science review were not affected by these changes. Appendix A of my science review for the alternative proportionality analysis used the incorrect sampling time, and will need to be re-run. However, this analysis was an alternative review and not presented in the science review itself or at the HSRB meeting.

Data Errors Identified

Dr. William Popendorf, a member of the Human Studies Review Board, noticed that there were inconsistencies between values of sampling duration and the amount of active ingredient handled (AaiH) reported in the study report (MRID 48210201, Appendix K) and in Table 2 of EPA's 4 October 2010 science review. These exceptions were called to EPA's attention via e-mail from Dr. Popendorf on November 1, 2010.

EPA has reviewed the values in question, has consulted with the Study Director and the QA Analyst at Golden Pacific Laboratories, and has determined that the AEATF's study report correctly reports sampling duration and AaiH for each subject in Tables 12, 13, and 14 (MRID 48210201 pp. 109-111). Table 84 of the same report (MRID 48210201 p. 181), however, attributed sampling times to the wrong subjects, as a result of confusing the subject number identification and the monitoring event assignment. That the error occurred in the transcription of data from Tables 12, 13, and 14 to Table 84 was confirmed by the study's QA Analyst.

In preparing Tables 2, 3, and 4 attached to EPA's 4 October 2010 science review, EPA matched the (incorrect) sampling times from Table 84 to the surface area mopped as reported in Tables 12, 13, 14 of the study report. This resulted in EPA incorrectly matching the surface area mopped to the MEs. The AEATF study report correctly reported the surface areas. EPA's summary statistics, however, were based on Tables 12, 13, and 14, and are correct.

Finally, the Study Director has reported to EPA that Appendix K included erroneous summary values of AaiH for subjects M8, M7, and M24. Again the values for these 3 subjects reported in study Tables 12, 13, 14 are correct. No AaiH errors were brought forward into EPA's analysis of the data.

Impact of the Identified Errors

The following consequences of the identified errors have been identified:

(1) Tables 2, 3, and 4 of the EPA Science Review memo must be corrected. Corrected tables are attached below, with revisions highlighted in yellow.

(2) Surface area of floor mopped was not used in the statistical analysis, and EPA presented only summary statistics for the surface area mopped to the HSRB. Since the actual surface area mopped values were correct, and the error was in the incorrect attribution of these correct values to particular subjects, the summary statistics were unaffected, the summary information presented to the HSRB was correct, and no corrections are needed.

(3) Task duration was used only in an alternative analysis of proportionality between dermal exposure and time. These results were summarized only in the statistical Appendix A to the EPA Science Review. EPA will re-run the alternative analysis and update Appendix A. EPA presented only summary statistics for the sampling time to the HSRB. Again since the actual values were correct, their incorrect attribution to subjects did not affect

the summary statistics. In this case, too, the information presented to the HSRB was correct.

(4) The AaiH for 3 subjects was reported incorrectly in the study report's Appendix K. The AaiH values were correct for these same subjects in study Tables 13 and 14. EPA used the correct values in its statistical analysis reported in the EPA Science Review and presented to the HSRB.

(5) Dr. Popendorf suggested at the HSRB meeting further investigation of the air sampling results taking sampling time into account. If Dr. Popendorf is considering further analysis himself, he will need the attached tables with corrected information for mopping time by subject. He should also note that air sampling pumps were turned on before mopping began and left on during breaks, so the pump time reported in Appendix K differs from the mopping time reported in the attached tables.

Attachments:

Table 2. Summary (Empirical) of Dermal and Inhalation Results for Mop—Long Pants, Long-sleeved Shirt, Shoes/socks, and No Gloves. (Corrected)

Table 3. Summary (Empirical) of Dermal Results for Mop—Long Pants, Short-sleeved shirt, Shoes/socks, and No Gloves. (Corrected)

Table 4. Summary (Empirical) of Dermal Results for Mop—Short Pants, Short-sleeved shirt, Shoes/socks, and No Gloves. (Corrected)

Table 2. Summary (Empirical) of Dermal and Inhalation Results for Mop—Long Pants, Long-sleeved Shirt, Shoes/Socks, and No Gloves

Cluster	Subject Order	Subject Number ID	Task Duration (minutes)	Surface Area (sq ft)	Number Buckets	Pounds ai Handled	Dermal Exposure (µg)	Inhalation Exposure (µg/m3)	Unit Exposures	
									Dermal (mg/lb ai)	Inhalation (µg/m3/lbai)
1	MW-01	M13	53	1884	3	0.00308	40.7	0.413	13.2	133.9
	MW-02	M6	85	5155	6	0.00669	42.8	0.334	6.4	49.9
	MW-03	M12	45	4997	3	0.00584	136.3	0.333	23.3	57.0
	MW-04	M28	59	5050	4	0.00538	289.4	0.209	53.7	38.8
	MW-05	M15	67	4189	5	0.00556	191.8	0.437	34.5	78.5
	MW-06	M27	31	3324	2	0.00419	75.7	0.292	18.1	69.7
		Mean	**57**	**4100**	**4**	**0.00513**	**129**	**0.336**	**24.9**	**71.3**
		Std	**19**	**1291**	**1**	**0.00129**	**98**	**0.083**	**17.0**	**33.7**
2	MW-07	M8	90	6688	6	0.00556226	66.9	0.123	12.0	22.1
	MW-08	M24	79	14191	5	0.01833364	154.3	0.107	8.4	5.8
	MW-09	M2	69	4952	5	0.00406091	66.9	0.108	16.5	26.6
	MW-10	M4	63	8295	4	0.0061509	162.7	0.242	26.5	39.3
	MW-11	M10	51	4390	4	0.00546085	112.3	0.216	20.6	39.6
	MW-12	M21	38	5884	3	0.00482371	134.3	0.128	27.8	26.5
		Mean	**65**	**7400**	**5**	**0.00740**	**116**	**0.154**	**18.6**	**26.7**
		Std	**19**	**3599**	**1**	**0.00540**	**42**	**0.0592**	**7.8**	**12.5**
3	MW-13	M7	89	6161	6	0.00838418	288.3	0.273	34.4	32.6
	MW-14	M18	79	5362	6	0.00703495	116.5	0.391	16.6	55.6
	MW-15	M26	69	4339	5	0.00740312	365.2	0.431	49.3	58.2
	MW-16	M14	59	5425	4	0.00699086	70.3	0.257	10.1	36.8
	MW-17	M20	49	4989	4	0.00528448	79.2	0.249	15.0	47.1
	MW-18	M1	38	4008	3	0.00392864	95.9	0.195	24.4	49.6
		Mean	**64**	**5047**	**5**	**0.00650**	**169**	**0.299**	**25.0**	**46.6**
		Std	**19**	**783**	**1**	**0.00161**	**125**	**0.091**	**14.7**	**10.2**
Overall		Mean	62	5516	4	0.00634	138	0.263	22.8	48.2
		Std	18	2553	1	0.00328	92	0.110	13.3	27.6
		Median	61	5023	4	0.00556	114	0.253	19.3	43.3
		Geo Mean	59	5094	4	0.00585	114	0.239	19.5	40.9
		95th%tile	89	9179	6	0.00988	301	0.432	50.0	86.8

Table 3. Summary (Empirical) of Dermal Results for Mop—Long Pants, Short-sleeved shirt, Shoes/socks, and No Gloves							
Cluster	Subject Order	Subject Number ID	Task Duration (minutes)	Surface Area (sq ft)	Number of Buckets	Pounds ai Handled	Unit Exposures Dermal (mg/lb ai)
1	MW-01	M13	53	1884	3	0.00308	20.3
	MW-02	M6	85	5155	6	0.00669	12.3
	MW-03	M12	45	4997	3	0.00584	25.2
	MW-04	M28	59	5050	4	0.00538	62.4
	MW-05	M15	67	4189	5	0.00556	40.3
	MW-06	M27	31	3324	2	0.00419	18.4
		Mean	**57**	**4100**	**4**	**0.00513**	**29.8**
		Std	**19**	**1291**	**1**	**0.00129**	**18.5**
2	MW-07	M8	90	6688	6	0.00556	12.6
	MW-08	M24	79	14191	5	0.01833	8.50
	MW-09	M2	69	4952	5	0.00406	17.5
	MW-10	M4	63	8295	4	0.00615	27.5
	MW-11	M10	51	4390	4	0.00546	24.9
	MW-12	M21	38	5884	3	0.00482	34.9
		Mean	**65**	**7400**	**5**	**0.00740**	**21.0**
		Std	**19**	**3599**	**1**	**0.00540**	**9.87**
3	MW-13	M7	89	6161	6	0.00838	35.3
	MW-14	M18	79	5362	6	0.00703	18.6
	MW-15	M26	69	4339	5	0.00740	55.2
	MW-16	M14	59	5425	4	0.00699	14.1
	MW-17	M20	49	4989	4	0.00528	15.8
	MW-18	M1	38	4008	3	0.00393	26.9
		Mean	**64**	**5047**	**5**	**0.00650**	**27.6**
		Std	**19**	**783**	**1**	**0.00161**	**15.6**
Overall		Mean	62	5516	4	0.00634	26.1
		Std	18	2553	1	0.00328	14.7
		Median	61	5023	4	0.00556	22.6
		Geo Mean	59	5094	4	0.00585	22.8
		95th%tile	89	9179	6	0.00988	56.3

Table 4. Summary (Empirical) of Dermal Results for Mop—Short Pants, Short-sleeved shirt, Shoes/socks, and No Gloves								
Cluster	Subject Order	Subject Number ID	Task Duration (minutes)	Surface Area (sq ft)	Number Buckets	Pounds ai Handled	Dermal Exposure (µg)	Unit Exposures Dermal (mg/lb ai)
1	MW-01	M13	53	1884	3	0.00308	82	26.4
	MW-02	M6	85	5155	6	0.00669	3690	551.2
	MW-03	M12	45	4997	3	0.00584	569	97.5
	MW-04	M28	59	5050	4	0.00538	565	104.9
	MW-05	M15	67	4189	5	0.00556	253	45.4
	MW-06	M27	31	3324	2	0.00419	103	24.7
		Mean	**57**	**4100**	**4**	**0.00513**	**877**	**141.7**
		Std	**19**	**1291**	**1**	**0.00129**	**1395**	**203.6**
2	MW-07	M8	90	6688	6	0.00556	698	125.5
	MW-08	M24	79	14191	5	0.01833	493	26.9
	MW-09	M2	69	4952	5	0.00406	227	56.0
	MW-10	M4	63	8295	4	0.00615	232	37.8
	MW-11	M10	51	4390	4	0.00546	400	73.2
	MW-12	M21	38	5884	3	0.00482	198	41.1
		Mean	**65**	**7400**	**5**	**0.00740**	**375**	**60.1**
		Std	**19**	**3599**	**1**	**0.00540**	**196**	**35.9**
3	MW-13	M7	89	6161	6	0.00838	789	94.1
	MW-14	M18	79	5362	6	0.00703	440	62.5
	MW-15	M26	69	4339	5	0.00740	505	68.2
	MW-16	M14	59	5425	4	0.00699	245	35.0
	MW-17	M20	49	4989	4	0.00528	152	28.8
	MW-18	M1	38	4008	3	0.00393	403	102.5
		Mean	**64**	**5047**	**5**	**0.00650**	**422**	**65.2**
		Std	**19**	**783**	**1**	**0.00161**	**222**	**29.9**
Overall		Mean	62	5516	4	0.00634	558	89.0
		Std	18	2553	1	0.00328	807	120
		Median	61	5023	4	0.00556	401	59.2
		Geo Mean	59	5094	4	0.00585	358	61.3
		95th%tile	89	9179	6	0.00988	1224	189